Health Status Benefits of Transcatheter vs. Surgical Aortic Valve Replacement in Patients with Severe Aortic Stenosis at Intermediate Surgical Risk

Results From The PARTNER 2 Trial

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Disclosure

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Background

• Improved quality of life (QOL) is a key goal of treatment for patients with severe AS and may be even more important than improved survival for many elderly patients

• Prior studies have shown that transcatheter aortic valve replacement (TAVR) results in substantial and durable QOL benefits in extreme risk/inoperable patients and an early QOL benefit compared with surgical aortic valve replacement (SAVR) in patients at high surgical risk

• However, the early QOL benefit of TAVR was confined to patients who were suitable for transfemoral access and was not seen in patients treated via the transapical approach
In the PARTNER 2A trial, TAVR was found to be non-inferior to SAVR for the primary endpoint of 2-year death or disabling stroke among patients at intermediate surgical risk.

There were differences in procedure-related complications and valve performance at 1 year, however, with some endpoints favoring TAVR and others favoring surgical AVR.

The overall impact of these alternative treatments on health-related QOL from the patient’s perspective has not yet been reported.
PARTNER 2A: Patient Population

Key Inclusion Criteria

- Severe, symptomatic AS (AVA < 0.8 cm² [or AVA-I ≤ 0.5 cm²/m²] and mean gradient > 40 mmHg or peak aortic jet velocity > 4.0 m/sec)
- “Intermediate Risk” → Predicted risk of operative mortality ≥ 4% based on heart team assessment

Key Exclusion Criteria

- LVEF < 20%
- CAD requiring revascularization with either unprotected left main dz or SYNTAX score > 32
- Serum creatinine > 3.0 mg/dl or hemodialysis
- Recent MI (1 month), stroke or TIA (6 months)
The PARTNER 2A Trial
Study Design

Symptomatic Severe Aortic Stenosis

ASSESSMENT by Heart Valve Team
Operable (STS ≥ 4%)

Randomized Patients
n=2032

ASSESSMENT:
Transfemoral Access

Yes

Transfemoral (TF)

1:1 Randomization (n=1550)

TF TAVR (n=775)

VS.

Surgical AVR (n=775)

No

Transapical (TA) / TransAortic (TAo)

1:1 Randomization (n=482)

TA/TAo TAVR (n=236)

VS.

Surgical AVR (n=246)

QOL assessed from all patients using validated questionnaires at baseline, 1 month, 1 year, and 2 years
Statistical Methods

• Study Population: All patients with baseline QOL data (n=1833, 90.2%)– analyzed by ITT

• Primary QOL Endpoint = KCCQ Overall Summary Score

• All other QOL scales considered secondary endpoints

• Scores between groups at each timepoint compared using analysis of covariance (ANCOVA), adjusting for baseline health status and access site

• Analytic plan specified that separate analyses would be performed for the transfemoral (TF) and transthoracic (TT) groups in case of a significant interaction between treatment effect and access site
## Baseline Characteristics

|                     | **TAVR**  
|                     | *(n = 950)* | **AVR**  
|                     | *(n = 883)* |
|---------------------|------------|------------|
| Age (yrs)           | 81 ± 7     | 81 ± 7     |
| Male gender         | 54.4%      | 55.4%      |
| STS risk score      | 5.8 ± 2.1  | 5.8 ± 1.8  |
| Prior MI            | 18.1%      | 17.9%      |
| Prior CABG          | 23.7%      | 25.6%      |
| Prior Stroke        | 10.2%      | 10.2%      |
| COPD (O₂ dependent) | 11.2%      | 9.7%       |
| Mean AVG (mmHg)     | 45 ± 13    | 45 ± 12    |

P = NS for all comparisons
Primary Endpoint
KCCQ Overall Summary

![Graph showing comparison between TAVR and SAVR]

- **TAVR**:
  - Δ = 11.4
  - P < 0.001

- **SAVR**:
  - Δ = -0.4
  - P = NS
  - Δ = 0.5
  - P = NS

Significant interaction (P<0.001) between treatment effect and access site for the primary endpoint and multiple secondary endpoints.
KCCQ Overall Summary (Primary Endpoint) TF Subgroup

Treatment Difference (TAVR - AVR)

1 month: \( \Delta = 14.1 \) P<0.001
12 months: \( \Delta = -0.1 \) P=NS
24 months: \( \Delta = 1.0 \) P=NS

P-values are for mean treatment effect of TAVR vs. SAVR
KCCQ Overall Summary (Primary Endpoint)

TT Subgroup

Treatment Difference (TAVR - AVR)

1 month 12 months 24 months

Δ = 3.5
P=NS

Δ = -0.5
P=NS

Δ = -1.2
P=NS

P-values are for mean treatment effect of TAVR vs. SAVR
KCCQ-Summary: Moderate or Substantial Improvement*: TF Subgroup

<table>
<thead>
<tr>
<th></th>
<th>1 month</th>
<th>1 year</th>
<th>2 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAVR</td>
<td>64.0%</td>
<td>71.1%</td>
<td>67.2%</td>
</tr>
<tr>
<td>SAVR</td>
<td>41.2%</td>
<td>68.9%</td>
<td>66.2%</td>
</tr>
</tbody>
</table>

* Improvement ≥ 10 points vs. baseline among patients with available QOL data

P < 0.001

P = NS
KCCQ-Summary: Moderate or Substantial Improvement*: TT Subgroup

P = NS at all timepoints

* Improvement ≥ 10 points vs. baseline among patients with available QOL data
Conclusions

• Taken together with previous data, these findings demonstrate that for intermediate risk patients suitable for a TF approach, TAVR provides both early and late benefits compared with surgical AVR from the patient’s perspective.

• The lack of benefit among patients ineligible for the TF approach suggests that a TT approach may not be preferable to SAVR in such patients—at least in the short to intermediate term.

• Further studies will be necessary to determine whether use of other alternative access sites (e.g., subclavian, carotid, transcaval) can overcome these limitations of the TT approach.